



# FINAL AGENDA

## 17<sup>TH</sup> ANNUAL U.S. FISH & WILDLIFE SERVICE AQUACULTURE DRUG APPROVAL COORDINATION WORKSHOP

WEEK OF AUGUST 1 – 4, 2011

THE BEST WESTERN GRANTREE INN



BOZEMAN, MONTANA

Hosted by: U.S. Fish & Wildlife Service (USFWS) -  
Aquatic Animal Drug Approval Partnership (AADAP) Program



Event Sponsors: AQUIS New Zealand Ltd., BL Mitchell Inc., Echelon, Frontier Scientific Inc., Merck Animal Health, PennField Animal Health, Syndel Laboratories, Inc., and Western Chemical, Inc.

Session Moderators: **Jim Bowker**, USFWS – AADAP Program, **Mark Gaikowski**, U.S. Geological Survey (USGS) Upper Midwest Environmental Sciences Center (UMESC)



### MONDAY, AUGUST 1<sup>st</sup>

- 8:00AM – 4:00PM Listening Session with FDA's Center for Veterinary Medicine to Develop Strategies to Resolve Drug Approval and Post Approval Issues (for more information email [jim\\_bowker@fws.gov](mailto:jim_bowker@fws.gov)), USFWS Bozeman Fish Technology Center
- 7:30AM – 4:00PM Early Registration at the USFWS Bozeman Fish Technology Center
- 4:00 – 8:00 PM **WELCOME SOCIAL AT MONTANA ALE WORKS** (downtown Bozeman) – sponsored by [Western Chemical, Inc.](#) and [Syndel Laboratories, Ltd.](#)

### TUESDAY, AUGUST 2<sup>nd</sup>

- 7:00 – 8:00 AM Workshop Registration
- 8:15 – 8:30 AM [Dave Erdahl](#)  
USFWS – AADAP Program [Howdy: Housekeeping and extracurricular activities](#)
- 8:30 – 8:45 AM [Stuart Leon](#)  
Division Chief, Fisheries &  
Aquatic Resource Conservation,  
USFWS Welcome – Keynote Address

### OVERVIEW PRESENTATION FROM CVM

- 8:45 – 9:00 AM [Cindy Burnsteel](#)  
Director, Division of Therapeutic  
Drugs for Food Animals,  
FDA/CVM [2011 Update from CVM](#)

### UPDATES

- 9:00 – 9:10 AM [David Bornholdt](#)  
USGS [Aquaculture drug research in the US Geological Survey:  
Agency perspectives](#)
- 9:10 – 9:20 AM [Steve Sharon](#)  
Chairman, AFWA-DAWG [Update from the AFWA Drug Approval Working Group](#)

## UPDATES (continued)

9:20 – 9:30 AM	<u>Jesse Trushenski</u> President, AFS-FCS	<u>AFS Fish Culture Section – A partner for progress in the aquaculture drug arena</u>
9:30 – 9:45 AM	<u>Jennifer Matysczak</u> FDA/CVM – Aquaculture Drugs Team	<u>Update from the Aquaculture Drugs Team</u>
9:45 – 10:05 AM	<b>BREAK</b> – sponsored by <u>Merck Animal Health</u>	
10:05 – 11:30 AM	<b>AQUAFLO<sup>®</sup></b> (florfenicol)	
	<u>Mark Gaikowski</u> USGS – UMESC	<u>Safety of AQUAFLO<sup>®</sup> (florfenicol) administered in feed to tilapia</u>
	<u>Mark Gaikowski</u> USGS – UMESC	<u>AQUAFLO<sup>®</sup> (florfenicol)-medicated feed administered to tilapia in a recirculating aquaculture system – depletion of FFC from RAS water and FFA from tilapia fillet tissue</u>
	<u>Molly P. Bowman</u> USFWS – AADAP Program	<u>Effectiveness of AQUAFLO<sup>®</sup> (50% Florfenicol) to control mortality of Chinook salmon caused by Bacterial Kidney Disease: An update from last summer</u>
	<u>Mark Gaikowski</u> USGS – UMESC	<u>Status of a residue depletion study in rainbow trout dosed with AQUAFLO<sup>®</sup> (florfenicol)-medicated feed at a rate of 20 mg/kg bodyweight</u>
	<u>Jim Bowker</u> USFWS – AADAP Program	Status of expanding label
11:30 AM – 1:00 PM	<b>LUNCH</b> – on your own	
1:00 – 2:00 PM	<b>35% PEROX-AID<sup>®</sup></b> (hydrogen peroxide)	
	<u>Mark Gaikowski</u> USGS – UMESC	<u>Use of 35% PEROX-AID<sup>®</sup> to reduce <i>Gyrodactylus salmosis</i> infestation</u>
	<u>Jim Bowker</u> USFWS – AADAP Program	<u>Efficacy of 35% PEROX-AID<sup>®</sup> to control infestations of <i>Gyrodactylus salmosis</i> in freshwater reared-rainbow trout</u>
	<u>Mark Gaikowski</u> USGS – UMESC	<u>Efficacy of 35% PEROX-AID<sup>®</sup> to control mortality caused by <i>Saprolegnia diclina</i> in walleye</u>
	<u>Grace Karreman</u> Aquatic Life Sciences	Status of expanding label
2:00 – 2:30 PM	<b>SLICE<sup>®</sup></b> (emamectin benzoate)	
	<u>Jim Bowker</u> USFWS – AADAP Program	<u>Use of SLICE<sup>®</sup> to reduce infestations of <i>Salmincola californiensis</i> in rainbow trout <i>Oncorhynchus mykiss</i></u>
	<u>Nicole Wandelaar</u> USFWS – AADAP Program	<u>Efficacy of SLICE<sup>®</sup> to control infestations of the parasite <i>Salmincola californiensis</i> in freshwater-reared rainbow trout – A field study</u>

## GENERAL PRESENTATIONS

2:30 – 2:45 PM	<u>Jennifer Love</u> FDA/CVM – Aquaculture Drugs Team	<u>The role of the project manager &amp; CVM's eSubmitter tool</u>
2:45 – 3:05 PM	<u>Guppy Blair</u> USFWS – Idaho FHC <u>Sonia Mumford</u> USFWS – Olympia FHC	<u>Judicious use of florfenicol and other antibiotics</u>

## GENERAL PRESENTATIONS (continued)

- 3:05 – 3:20 PM Phil Klesius  
USDA – ARS [An in vitro screening method to evaluate chemicals as potential chemotherapeutants to control \*Aeromonas hydrophila\* infection in channel catfish](#)
- 3:20 – 3:35 PM **CHANNEL CATFISH PITUITARY**  
Jim Bowker  
USFWS – AADAP Program [Efforts to gain FDA approval of Channel Catfish Pituitary as a spawning aid](#)  
Roger Yant  
Hybrid Catfish Company Status of CP
- 3:35 – 3:50 PM **BREAK** – sponsored by AQUI-S New Zealand, Ltd.
- 3:50 – 5:00 PM **ROUND-TABLE DISCUSSION WITH CVM**
- 6:00 – 9:00 PM **ICE-BREAKER BBQ AT THE USFWS BOZEMAN FISH TECHNOLOGY CENTER**  
sponsored by BL Mitchell Inc.  
\*Please ride the free Yellow Bus! It will leave the GranTree Inn at 5:45pm.

## WEDNESDAY, AUGUST 3<sup>rd</sup>

- 8:15 – 8:30 AM **MASCULINIZING FEED FOR TILAPIA<sup>®</sup>** (17  $\alpha$ -methyltestosterone)  
Molly P. Bowman  
USFWS – AADAP Program [The safety of 17  \$\alpha\$ -methyltestosterone administered in feed to Nile tilapia: Histology Results](#)  
Mark Gaikowski  
USGS – UMESC [Status of the method transfer study for determining 17  \$\alpha\$ -methyltestosterone concentrations in feed](#)  
Dave Erdahl  
USFWS – AADAP Program [Status of 17MT data requirements](#)
- 8:30 – 8:45 AM **HALAMID<sup>®</sup>** (chloramine-T)  
Mark Gaikowski  
USGS – UMESC [Status of the modified method to determine p-TSA \(the chloramine-T marker residue\) concentrations in fillet tissue](#)  
TBA  
to be announced Update on initial approval

## GENERAL PRESENTATIONS

- 8:45 – 9:45 AM Sanja Modric  
FDA/CVM – Antiparasitic and Physiologic Drugs Team [CVM's drug approval process for aquatic species: Use of pharmacokinetics](#)
- 9:45 – 10:05 AM **BREAK** – sponsored by Merck Animal Health
- 10:05 – 10:30 AM Holly Erdely  
FDA/CVM – HFS Residue Chemistry Team [Food Use Authorizations](#)
- 10:30 – 11:30 AM **AFS FISH CULTURE SECTION WORKING GROUP ON AQUACULTURE DRUGS, CHEMICALS AND BIOLOGICS**
- 11:30 AM – 1:00 PM **LUNCH** – on your own
- 1:00 – 2:30 PM **AQUI-S<sup>®</sup>20E** (eugenol)  
Mark Gaikowski  
USGS – UMESC [Update of UMESC activities with AQUI-S<sup>®</sup>20E and/or eugenol](#)  
Jim Bowker  
USFWS – AADAP Program [Eugenol in water](#)

1:00 – 2:30 PM	<b>AQUI-S® 20E (continued)</b> <u>Jim Bowker</u> USFWS – AADAP Program <u>Molly P. Bowman</u> USFWS – AADAP Program <u>Jesse Trushenski</u> Southern Illinois University <u>Tom Goodrich</u> AQUI-S New Zealand, Ltd.	<u>Effectiveness of AQUI-S® 20E and BENZOAK® as fish sedatives</u> <u>Reducing the histology data requirements for AQUI-S® 20E Target Animal Safety studies</u> <u>Chemical and electrosedation of warm- and coolwater fishes</u>  AQUI-S® 20E: Sponsor update
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## GENERAL PRESENTATIONS

2:30 – 2:50 PM	<u>Stuart Jeffrey</u> FDA/CVM – Office of Minor Use for Minor Species	<u>MUMS: Grants Update</u>
2:50 – 3:10 PM	<u>Cindy Burnsteel</u> Division of Therapeutic Drugs for Food Animals, FDA/CVM	<u>Who's Who in CVM?</u> <u>Probiotics, or preferably, Direct-Fed Microorganism (DFM)</u>
3:10 – 3:25 PM	<u>Ken Cain</u> University of Idaho	<u>Identification of specific autochthonous probiotics capable of enhancing resistance to bacterial coldwater disease (CWD) in rainbow trout</u>
3:25 – 3:40 PM	<b>BREAK</b> – sponsored by <u>Merck Animal Health</u>	

## BIOLOGICS PRESENTATIONS

3:40 – 3:55 PM	<u>Julia Pridgeon</u> USDA – ARS	<u>Development and efficacy of a novobiocin-resistant <i>Streptococcus iniae</i> as a novel vaccine in Nile tilapia (<i>Oreochromis niloticus</i>)</u>
3:55 – 4:10 PM	<u>Hugh Mitchell</u> Aquatic Life Sciences	<u>Current fish vaccine regulations and policies: What is and isn't working for fish culturists</u>
4:10 – 4:25 PM	<u>Mike Matthews</u> Florida FWCC	<u>AquaVac-Col™, <i>Flavobacterium columnare</i> vaccine use on catfish at the Richloam Fish Hatchery 2006 – 2011</u>
4:25 PM	<b>DOOR PRIZE DRAWING</b> – sponsored by <u>Frontier Scientific Inc./Echelon</u>	
6:30 PM	<b>2<sup>ND</sup> ANNUAL WORKSHOP TROUT TROT</b> – sponsored by <u>Aquatic Life Sciences, Inc.</u> *Choose from a 1, 3, or 5 mile fun run/walk – meet at Bozeman's Bogert Park near downtown. The fun run/walk is free and everyone is welcome!	

## THURSDAY, AUGUST 4<sup>th</sup>

8:15 – 8:30 AM	<b>TERRAMYCIN® 200 FOR FISH</b> (oxytetracycline-medicated feed) <u>Niccole Wandelea</u> USFWS – AADAP Program <u>Mark Gaikowski</u> USGS – UMESC	<u>Efficacy of Terramycin® 200 for Fish to control mortality in largemouth bass caused by columnaris disease</u> <u>Efficacy of TM-200® for Fish or AQUAFLO® to control mortality from Motile Aeromonad Septicemia</u>
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## GENERAL PRESENTATIONS

8:30 – 9:00 AM	<u>Dottie McAdams</u> FDA/CVM – Office of Surveillance and Compliance	<u>Office of Surveillance and Compliance</u>
9:00 – 9:15 AM	<u>Bonnie Johnson</u> USFWS – AADAP Program	<u>Overview of the INAD Program Management System (Online Data Reporting)</u>

**GENERAL PRESENTATIONS (continued)**

- 9:15 – 9:25 AM Jim Bowker AADAP Drug Research Information Bulletins  
USFWS – AADAP Program
- 9:25 – 9:40 AM Jim Powell Recreation and conservation hatcheries need drugs too  
Freshwater Fisheries  
Society of BC
- 9:40 – 10:00 AM **BREAK** – sponsored by USFWS – AADAP Program
- 10:00 – 11:00 AM **WRAP-UP & DISCUSSION**  
Plans for 18<sup>th</sup> Annual USFWS Aquaculture Drug Approval Coordination Workshop
- 11:00 AM **DOOR PRIZE DRAWING** – sponsored by Frontier Scientific Inc./Echelon
- 12:00 – 6:00 PM **DECOMPRESSION RAFTING TRIP ON THE YELLOWSTONE RIVER** –  
sponsored by PennField Animal Health  
\*Leave the GranTree Inn at 12:00pm, must be on the river ready-to-float by 1:30pm  
(~60 min drive to the river). River-side picnic to follow float.